DEPARTMENT OF MENTAL HEALTH, MENTAL RETARDATION AND SUBSTANCE ABUSE SERVICES
OFFICE OF SUBSTANCE ABUSE SERVICES
GUIDANCE BULLETIN NO. 2007-02
ISSUE DATE: JUNE 8, 2007

TITLE: BUPRENORPHINE PRODUCTS FOR THE PHARMACOLOGIC MANAGEMENT OF OPIOID ADDICTION (REVISED)

[ ] ADVISORY (BEST PRACTICES)
[X] MANDATE (REQUIREMENT)

RECIPIENTS:

- Community Services Boards (CSBs) and Behavioral Health Authorities (BHAs) – Executive Directors
- Community Services Boards (CSBs) and Behavioral Health Authorities (BHAs) – Substance Abuse Directors
- CSB Physicians
- Facility Medical Directors
- Opioid Treatment Program Directors

PURPOSE:

1. To inform CSBs of the availability of buprenorphine from the Community Pharmacy.
2. To provide additional information about buprenorphine for pharmacological treatment of opioid addiction to CSBs interested in expanding their continuum of care for the treatment of opioid addiction.
3. To provide resources to assist system physicians, nurses and clinicians in finding buprenorphine training.
4. To provide resources for the development of policies, procedures and protocols for the practice management of using buprenorphine.
5. To familiarize CSBs with Community Pharmacy Policies as they relate to practice management of using buprenorphine.

BACKGROUND: The Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS) recognizes that the prevalence of addiction to heroin and other opioids has risen sharply in the United States and that the residents of the Commonwealth of Virginia should have access to modern, appropriate and effective addiction treatment. The appropriate application of up-to-date knowledge and treatment modalities can successfully treat patients who suffer from opioid addiction and reduce the morbidity, mortality and costs associated with opioid addiction, as well as public health problems such as HIV, HBV, HCV and other infectious diseases. DMHMRSAS encourages all physicians to assess their patients for a history of substance abuse and potential opioid addiction. DMHMRSAS has developed these guidelines in an effort to balance the need to expand

treatment capacity for opioid addicted patients with the need to prevent the inappropriate, unwise or illegal prescribing of opioids.

POLICY:

❑ ACCESSING BUPRENORPHINE THROUGH COMMUNITY RESOURCE PHARMACY

Effective immediately Buprenorphine (Suboxone) is available through the Community Pharmacy system for eligible consumers. To access buprenorphine for eligible consumers, follow the guidelines provided in the attached policies. (See Community Resource Pharmacy Policies 3 and 12, Appendices A and B).

❑ PHYSICIAN QUALIFICATIONS

Until recently, physicians have been prohibited from prescribing and dispensing opioid medications in the treatment of opioid addiction, except within the confines of federally regulated opioid treatment programs. Because of the increasing number of opioid-addicted individuals and the associated public health problems, as well as the limited availability of addiction treatment programs, federal laws now enable qualified physicians to prescribe Schedule III-V medications approved by the Food and Drug Administration for office-based treatment of opioid addiction].[1]

Physicians who consider office-based treatment of opioid addiction must be able to recognize the condition of drug or opioid addiction and be knowledgeable about the appropriate use of opioid agonist, antagonist, and partial agonist medications. Physicians must also possess the required qualifications as defined under and in accordance with the "Drug Addiction Treatment Act of 2000" (DATA) (Public Law 106-310, Title XXXV, Sections 3501 and 3502) and obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA). In order to qualify for a waiver, physicians must hold a current license in the Commonwealth of Virginia and, at a minimum, meet one or more of the following conditions to be considered as qualified to treat opioid addicted patients in an office-based setting in the Commonwealth:

- Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties
- Subspecialty board certification in addiction medicine from the American Osteopathic Association
- Addiction certification from the American Society of Addiction Medicine
- Completion of not less than 8 hours of training related to the treatment and management of opioid-dependent patients provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or other organization approved by the board.

[1] Drug Addiction Treatment Act of 2000, Public Law 106-310, Title XXXV, Section 3501 and 3502.

- Participation as an investigator in one or more clinical trials leading to the approval of a narcotic drug in Schedule III, IV, or V or a combination of such drugs for treatment of opioid addicted patients (must be evidenced by a statement submitted to the Secretary of the U.S. Department of Health and Human Services by the sponsor of such approved drug).
- Additional qualification criteria may be added through legislative enactment.

In addition to the waiver, physicians must have a valid Drug Enforcement Administration (DEA) registration number and a DEA identification number that specifically authorizes such office-based treatment.

The waiver to provide addiction treatment under DATA is granted by the Secretary of the U.S. Department of Health and Human Services, presumably through SAMHSA, no later than 45 days after receipt of the physician's written notification. Upon request from SAMHSA, the Attorney General, presumably through DEA, will automatically assign the physician an identification number that will be used with the physician's DEA registration number. However, if SAMHSA has not acted on the physician's request for a waiver by the end of this 45-day period, DEA will automatically assign the physician an identification number.

Furthermore, if a physician wishes to prescribe or dispense narcotic drugs for maintenance or detoxification treatment on an emergency basis in order to facilitate the treatment of an individual patient before the 45-day waiting period has elapsed, the physician musty notify SAMHSA and the DEA of the physician's intent to provide such treatment.

DMHMRSAS recognizes that new treatment modalities offer an alternative in the treatment of opioid addiction. Based on appropriate patient assessment and evaluation, it may be both feasible and desirable to provide office-based treatment of opioid addicted patients with Schedules III–V opioid medications approved for such use by the FDA and regulated in such use by Center for Substance Abuse Treatment (CSAT/SAMHSA). Physicians are referred to the Buprenorphine Clinical Practice Guidelines, available at the CSAT/SAMHSA, Office of Pharmacologic and Alternative Therapies, Rockwall II, Room 7-222, 5515 Security Lane, Rockville, MD 20857; (301) 443-7614 or http://dpt.samhsa.gov.

The medical recognition and management of opioid addiction should be based upon current knowledge and research that includes the use of both pharmaceutical and non-pharmaceutical modalities. Prior to initiating treatment, physicians should be knowledgeable about addiction treatment and all available pharmacologic treatment agents as well as available ancillary services to support both the physician and patient. In order to undertake treatment of opioid addicted patients, in accordance with these guidelines, physicians must demonstrate a capacity to refer patients for appropriate counseling and other ancillary services.

DMHMRSAS recognizes that inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate and nonmedical uses.

Qualified physicians need not fear disciplinary action from DMHMRSAS or other state regulatory or enforcement agency for appropriate prescribing, dispensing or administering approved opioid drugs in Schedules III, IV, or V, or combinations thereof, for a legitimate medical purpose in the usual course of opioid addiction treatment. DMHMRSAS will consider appropriate prescribing, ordering, administering, or dispensing of these medications for opioid addiction to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of opioid addiction and in compliance with applicable state and federal law.

DMHMRSAS will determine the appropriateness of prescribing based on the physician's overall treatment of the patient and on available documentation of treatment plans and outcomes. The goal is to document and treat the patient's addiction while effectively addressing other aspects of the patient's functioning, including physical, psychological, medical, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what DMHMRSAS considers to be within the boundaries of accepted professional practice.

GUIDELINES

DMHMRSAS has adopted the following guidelines when evaluating the documentation and treatment of opioid addiction under DATA:

- ❑ **COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS**

  Generally, to prescribe and dispense Schedules III–V opioid medications for the treatment of opioid addiction under DATA, the physician must be licensed in the state, have a valid DEA controlled substances registration and identification number, comply with federal and state regulations applicable to controlled substances, and have a current waiver issued by SAMHSA. To obtain this waiver, the physician must submit written notification to the Secretary of HHS of their intent to provide this treatment modality, certifying the physician's qualifications and listing his/her DEA registration number. SAMHSA will then notify DEA whether a waiver has been granted. If SAMHSA grants the physician a waiver, DEA will issue the qualifying physician an identification number. In addition to these requirements, the DATA limits the number of patients that a physician may treat is 100.

  Physicians are specifically prohibited from delegating prescribing opioids for detoxification and/or maintenance treatment purposes to non-physicians. Physicians are referred to DEA regulations (21CFR, Part 1300 to end) and the DEA Physician's Manual www.deadiversion.usdoj.gov and (any relevant documents issued by the state

medical board) for specific rules governing issuance of controlled substances prescriptions as well as applicable state regulations.

❑ **EVALUATION OF THE PATIENT**

A recent, complete medical history and physical examination must be documented in the medical record. The medical record should document the nature of the patient's addiction(s), evaluate underlying or coexisting diseases or conditions, the effect on physical and psychological function, and history of substance abuse and any treatments therefore. The medical record should also document the suitability of the patient for office-based treatment based upon recognized diagnostic criteria.[2]

DSM-IV-TR Substance Dependence Criteria[3]

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

- Tolerance, as defined by either of the following:
  - A need for markedly increased amounts of the substance to achieve intoxication or desired effect, or
  - Markedly diminished effect with continued use of the same amount of the substance.

- Withdrawal, as manifested by either of the following:
  - the characteristic withdrawal syndrome for the substance, or
  - the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms
- The substance is often taken in larger amounts or over longer period than was intended.

- There is a persistent desire or unsuccessful efforts to cut down or control substance use.

- A great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain-smoking), or recover from its effects.

- Important social, occupational or recreational activities are given up or reduced because of substance use.

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[2] Buprenorphine Clinical Practice Guidelines, Table 3-1.

[3] American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 4th ed., Text Revision, Washington, D.C.

- The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption)

❑ **TREATMENT PLAN**

The written treatment plan should state objectives that will be used to determine treatment success, such as freedom from intoxication, improved physical function, psychosocial function and compliance and should indicate if any further diagnostic evaluations are planned, as well as counseling, psychiatric management or other ancillary services. This plan should be reviewed periodically. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Treatment goals, other treatment modalities or a rehabilitation program should be evaluated and discussed with the patient. If possible, every attempt should be made to involve significant others or immediate family members in the treatment process, with the patient's consent. The treatment plan should also contain contingencies for treatment failure (i.e., due to failure to comply with the treatment plan, abuse of other opioids, or evidence that the Schedules III–V medications are not being taken).

❑ **INFORMED CONSENT AND AGREEMENT FOR TREATMENT**

The physician should discuss the risks and benefits of the use of these approved opioid medications with the patient and, with appropriate consent of the patient, significant other(s), family members, or guardian. The patient should receive opioids from only one physician and/or one pharmacy when possible. The physician should employ the use of a written agreement between physician and patient addressing such issues as (1) alternative treatment options; (2) regular toxicologic testing for drugs of abuse and therapeutic drug levels (if available and indicated); (3) number and frequency of all prescription refills and (4) reasons for which drug therapy may be discontinued (i.e., violation of agreement).

❑ **PERIODIC PATIENT EVALUATION**

Patients should be seen at reasonable intervals (at least weekly during initial treatment) based upon the individual circumstance of the patient. Periodic assessment is necessary to determine compliance with the dosing regimen, effectiveness of treatment plan, and to assess how the patient is handling the prescribed medication. Once a stable dosage is achieved and urine (or other toxicologic) tests are free of illicit drugs, less frequent office visits may be initiated (monthly may be reasonable for patients on a stable dose of the prescribed medication(s) who are making progress toward treatment objectives). Continuation or modification of opioid therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as: (1) absence of toxicity; (2) absence of medical or behavioral adverse effects; (3) responsible handling of medications; (4) compliance with all elements of the

treatment plan (including recovery-oriented activities, psychotherapy and/or other psychosocial modalities); and (5) abstinence from illicit drug use. If reasonable treatment goals are not being achieved, the physician should re-evaluate the appropriateness of continued treatment.

- ❑ **CONSULTATION**

  The physician should refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The physician should pursue a team approach to the treatment of opioid addiction, including referral for counseling and other ancillary services. Ongoing communication between the physician and consultants is necessary to ensure appropriate compliance with the treatment plan. This may be included in the formal treatment agreement between the physician and patient. Special attention should be given to those patients who are at risk for misusing their medications and those whose living or work arrangements pose a risk for medication misuse or diversion. The management of addiction in patients with comorbid psychiatric disorders requires extra care, monitoring, documentation and consultation with or referral to a mental health professional.

- ❑ **MEDICAL RECORDS**

  The prescribing physician should keep accurate and complete records to include (1) the medical history and physical examination; (2) diagnostic, therapeutic and laboratory results; (3) evaluations and consultations; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments; (7) medications (including date, type, dosage, and quantity prescribed and/or dispensed to each patient); (8) a physical inventory of all Schedules III, IV, and V controlled substances on hand that are dispensed by the physician in the course of maintenance or detoxification treatment of an individual; (9) instructions and agreements; and (10) periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review. The physician must adhere to the special confidentiality requirements of 42CFR, Part 2, which apply to the treatment of drug and alcohol addiction, including the prohibition against release of records or other information, except pursuant to a proper patient consent or court order in full compliance with 42CFR2, or the Federal or State officials listed in 42CFR2, or in cases of true medical emergency or for the mandatory reporting of child abuse.

SOURCES OF FURTHER INFORMATION:

FOR POLICY & PROCEDURE AND PROTOCOL DEVELOPMENT:

For Policy and Procedure development see *Community Resource Pharmacy Policy #12* (Appendix A) and *Community Resource Pharmacy Policy #3* (Appendix B). For protocol development we recommend the use of *TIP 40:Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Downloadable copies are available at: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.72248). The Suboxone Practice Management Tool Kit ©2006, (available through Reckitt Benckiser) is recommended

for Boards beginning the use of Buprenorphine and is available by contacting: http://www.suboxone.com/Default.aspx). Additional information is provided on the SAMHSA Buprenorphine Web site: http://buprenorphine.samhsa.gov/index.html .

TRAINING:

- **FOR PHYSICIANS:**

  On-Line Training

  1. www.docoptin.com
  2. www.buprenorphinecme.com
  3. http://www.aaap.org/buprenorphine//burnorphine.htm

  CD-ROM Based Training Course

  1. American Academy of Addiction Psychiatry: "Buprenorphine in the Treatment of Opioid Dependence"
  2. To Order CD-ROM: e-mail www.aaap.org or call (202)393-44484

  Live Training - Opt-in

  1. www.docoptin.com
  2. For Information on the website mail to: info/docoptin.com

  Study Groups or "Hybrid Course"

  1. Complete 4 Hours of Live Training
  2. Courses must meet the 8 Hour Training requirement specified in the Drug Addiction Treatment Act of 2000
  3. For further details email Anthony Dekker, DO, FAOAAM: Anthony.Dekker@his.org

- **FOR COUNSELORS:**

  Buprenorphine Treatment of Opioid Addiction—A Counselor's Guide, prepares counselors as they guide patients and their families on the use of buprenorphine in office-based and other healthcare and substance abuse treatment settings. Counselors learn about the effects, efficacy, and safety of buprenorphine. Counselors will also gain an understanding of their partnership with physicians as part of the therapeutic team providing opioid addiction treatment with buprenorphine.

  To register or to learn more about the 3-contact-hour course, please visit the Central East Addiction Technology Transfer Center and click on the graphic that reads "online courses."

APPENDIX A

VIRGINIA DEPARTMENT OF MENTAL HEALTH, MENTAL RETARDATION AND SUBSTANCE ABUSE SERVICES

COMMUNITY RESOURCE PHARMACY POLICY #12

SUBJECT: Buprenorphine/Naloxone (Suboxone®) Procedures

PURPOSE: To establish policy and procedural guidelines/requirements for the use of Buprenorphine/Naloxone (Suboxone®)

CANCELLATION: All previous policies and statements are canceled.

PROCEDURE:

1. **Prescriber's Requirements:**

   A. ***All*** prescribers writing for Buprenorphine/Naloxone must be approved by and registered with the Substance Abuse and Mental Health Services Administration (SAMHSA).

   B. Prescribers must be registered with the Drug Enforcement Administration (DEA) and be assigned a separate and unique DEA number specific to Buprenorphine/Naloxone, in addition to their regular DEA number.

   C. Prescribers must have a bona-fide contractual affiliation with a Community Service Board and must be registered on the CSB/BHA Affiliated Physician Registration Form.

   D. Prescribers must have completed and submitted a Community Resource Pharmacy Physician Registration form to the CRP. The completed form must provide all required licensing information/numbers (i.e. DEA Registration Numbers (2), VA License#, and Medicaid Presbriber #).

2. **Prescription Requirements:**

   A. All new prescription orders for Buprenorphine/Naloxone ***must be written on a separate DMH265 prescription order card.*** Buprenorphine/Naloxone is a Schedule III – Controlled Substance and ***must be ordered separate and apart from all other Scheduled medications (CIV-CVI).***

B. ***All orders must clearly list both of the Prescriber's DEA Registration numbers (i.e. AS1234567 and XS1234567).*** Any order received, by the CRP, that does not list both numbers ***will be returned to the CSB of origin.***

C. Prescription orders must be written utilizing the product's generic title Buprenorphine/Naloxone or the branded title Suboxone®. ***(orders written for Subutex® will not be accepted by the CRP).***

D. The Community Resource Pharmacy will dispense this Schedule III product in a 30 day unit-of-use supply in accordance with established CRP Policy (Policy #10). ***Orders should be written for a 30 day quantity.***

E. Refill orders for Buprenorphine/Naloxone will be permitted and must be requested on a ***separate refill request form*** from all other medications.

3. Delivery procedures:

A. Buprenorphine/Naloxone will be shipped, to the CSB, separate and apart from ***ALL*** other medications.

B. Ideally, the CRP would like to establish a once-a-week Buprenorphine/Naloxone dispensing day for all CSB delivery sites. To assist the CRP, in creating a delivery system that restricts multiple package deliveries, the CSB should limit their Buprenorphine/Naloxone ordering to once-a-week.

EFFECTIVE DATE: February 2007

John E. Wall, R.Ph.
Pharmacy Manager

APPENDIX B

VIRGINIA DEPARTMENT OF MENTAL HEALTH, MENTAL RETARDATION AND SUBSTANCE ABUSE SERVICES

COMMUNITY RESOURCE PHARMACY POLICY #3

SUBJECT: Clients served by the Community Resource Pharmacy

PURPOSE: To offer guidelines in determining client's eligibility to receive Pharmacy services

CANCELLATION: All previous policy statements are canceled

The Community Resource Pharmacy's services are restricted to those clients of Community Service Board Mental Health Clinics/Centers, and Substance Abuse/Alcoholism Treatment Centers and Dept. of MHMRSAS approved Crisis Stabilization Treatment Centers, who are medically indigent or whose families or guardians are financially unable to purchase psychotropic medication. The Community Resource Pharmacy's formulary is restricted to Psychotropic Medications (medications primarily prescribed for treatment of a MH, MR, or SAS diagnosis).

I. AFTERCARE PROGRAM

The Community Resource Pharmacy is restricted by Section 37.1-101 of the Code of Virginia. A copy of which is attached to Policy Statement #1. The Code allows that the Department of Mental Health, Mental Retardation, and Substance Abuse Services **may** provide psychotropic medication(s) to former patients of State Psychiatric Hospitals or Training Centers **"if such patient or the person legally liable for his care and treatment is financially unable to pay for drugs or medicines which are prescribed for him. . . in order to mitigate a recurrence of the condition for which he has received care and treatment. . ."**

II CLINIC OR COMMUNITY IN-TAKE PROGRAM

The Clinic or Community In-take program is restricted to those clients of Community Service Board operated Mental Health Centers or Clinics **who lack the financial ability** (less than or equal to 200% of the Federal Poverty Level) to purchase psychotropic medications for treatment and the client has never been hospitalized in a State Psychiatric Hospital, Training Center, or Substance Abuse Program. The cost of the medication for such clients is charged to the clinic of origin.

III ALCOHOLISM SERVICE PROGRAM

Clients of Alcoholism Service Programs may be eligible to receive psychotropic medication from the Community Resource Pharmacy if they meet the conditions stated above for Aftercare or Clinic.

IV INTERSTATE TRANSFER ELIGIBILITY (ITCA)

It has been the policy of the Department to provide follow-up care for persons now residing in Virginia who were hospitalized in a State Mental Hospital in another state. The providing of such service has been contingent upon approval by the Central Office.

Prior to dispensing psychotropic medication to residents of Virginia who were hospitalized in a State Psychiatric Hospital in another state, before moving to Virginia, the Pharmacy must have on file an approval request for aftercare eligibility.

In order for such requests to be approved, the information contained in the request must establish:

1. That the patient was discharged from an out-of-state State Psychiatric Hospital within a sixty (60) day period, or

2. that the patient was discharged from an out-of-state State Psychiatric Hospital and has been receiving follow-up care by that State since discharge, and

3. the patient is financially unable to purchase psychotropic medications from other sources, and

4. treatment records or transcripts of prior treatment and hospitalization are available or have been requested of the former state.

Requests for Interstate Transfer medication eligibility should be mailed to the attention of the Manager of the Community Resource Pharmacy.

V. MEDICAID ELIGIBILITY

Clients who are Medicaid eligible may receive psychotropic medication through the Community Resource Pharmacy if they meet the conditions stated previously for Aftercare or Clinic clients.

EFFECTIVE DATE: January 2006
Revised 7/06

John E. Wall, R.Ph.
Pharmacy Manager

APPENDIX C

DEFINITIONS

For the purposes of these guidelines, the following terms are defined as follows:

- **ADDICTION:** A primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm and craving.

- **AGONISTS:** Agonist drugs are substances that bind to the receptor and produce a response that is similar in effect to the natural ligand that would activate it. Full mu opioid agonists activate mu receptors, and increasing doses of full agonists produce increasing effects. Most opioids that are abused, such as morphine and heroin, are full mu opioid agonists.

- **"APPROVED SCHEDULE III-V OPIOIDS":** Opioids referred to by the DATA, specifically approved by the FDA for treatment of opioid dependence or addiction.

- **ANTAGONISTS:** Antagonists bind to but do not activate receptors. They prevent the receptor from being activated by an agonist compound. Examples of opioid antagonists are naltrexone and naloxone.

- **MAINTENANCE TREATMENT:** Maintenance treatment means the dispensing for a period in excess of 21 days of an opioid medication(s) at stable dosage levels in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

- **OPIOID DEPENDENCE:** A maladaptive pattern of substance use, leading to clinically significant impairment or distress, manifested by 3 or more of the following, occurring at any time in the same 12-month period:

    - A need for markedly increased amounts of the substance to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount of substance;
    - The characteristic withdrawal syndrome for the substance or the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms;
    - The substance was taken in larger amounts or over a longer period of time than was intended;
    - There is a persistent desire or unsuccessful efforts to cut down or control substance use;
    - Significant time is spent on activities to obtain the substance, use the substance, or recover from its effects;

- Important social, occupational, or recreational activities are discontinued or reduced because of substance use;
- Substance use is continued despite knowledge of having a persistent physical or psychological problem that is caused or exacerbated by the substance.

- **OPIOID DRUG:** Opioid drug means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction sustaining liability. (This is referred to as an opiate in the Controlled Substances Act.)

- **OPIOID TREATMENT PROGRAM** (OTP) (sometimes referred to as a methadone clinic or narcotic treatment program): Opioid treatment program means a licensed program or practitioner engaged in the treatment of opioid addicted patients with approved Scheduled II opioids (methadone).

- **PARTIAL AGONISTS:** Partial agonists occupy and activate receptors. At low doses, like full agonists, increasing doses of the partial agonist produce increasing effects. However, unlike full agonists, the receptor-activation produced by a partial agonist reaches a plateau over which increasing doses do not produce an increasing effect. The plateau may have the effect of limiting the partial agonist's therapeutic activity as well as its toxicity. Buprenorphine is an example of a partial agonist.

- **PHYSICAL DEPENDENCE:** A state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

- **QUALIFIED PHYSICIAN:** A physician, licensed in the Commonwealth of Virginia who holds a current waiver issued by SAMHSA (as authorized by the Secretary of the U.S. Department of Health and Human Services (HHS) and meets one or more of the conditions set forth in Section 1. In addition, a physician must have a valid DEA registration and identification number authorizing the physician to conduct office-based treatment.

- **SUBSTANCE ABUSE:** A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one or more of the following, occurring within a 12-month period:

  - Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home;
  - Recurrent substance use in situations in which it is physically hazardous;
  - Recurrent substance-related legal problems;
  - Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance.

- **TOLERANCE:** A state of adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time.

- **WAIVER:** A documented authorization from the Secretary of the U.S. Department of Health and Human Services (HHS) issued by the Substance Abuse and Mental Health Services Administration under the Drug Addiction Treatment Act of 2000 (DATA 2000) that exempts qualified physicians from the rules applied to Opioid Treatment Programs (OTPs). Implementation of the waiver includes possession of a valid Drug Enforcement Administration (DEA) certificate with applicable suffix.

APPENDIX D

FROM: Tetrick, Frank

SENT: Friday, June 01, 2007 12:07 PM

To: Brian Duncan; Buddy Hall; Candy Waller; Charlotte McNulty; Chuck Hall; Chuck Walsh; Cindy Kemp; David Coe (E-mail); Demetrios Peratsakis; Dennis Cropper; George Braunstein; George Pratt; Jack Thomasson (E-mail); Jeff Fox (E-mail); Jerry Thomas; Jim Cannon; Jim Sikkema; Jim Thur; Jim Tobin; Joe Fuller (E-mail); Joe Hubbard; Joe Saregant; Lenard Lackey; Les Saltzberg (E-mail); Lisa Moore; Mike Gilmore (E-mail); Mike O'Connor; Nancy E. Cottingham (E-mail); Robert Johnson (E-mail); Ron Allison; Ron Branscome; Sam Dillon; Steve Ashby; Susan Bergquist; Terry Jenkins; Tom Geib; Tom Maynard; Tom Slaven; Will Rogers; William Park

Cc: Reinhard, James; Ratke, Ray; Deans, Jerry; VACSB (E-mail); Asha Mishra (E-mail); Colton Hand; Evans, James; Forbes, Ronald; Gardella, Robert; Jackson, John; Kent McDaniel (E-mail); Kirk Morton (E-mail); MA Marina Sinyard RN (E-mail); Margaret Sellers (E-mail); Stone, James R.; Tetrick, Frank; Thomas, Michele Rx; Wall, John; Yeh, Joy

SUBJECT: COMMUNITY RESOURCE PHARMACY UPDATE - PLEASE DISTRIBUTE

As we near the end of the fiscal year, I'd like to update you on several areas related to the Community Resource Pharmacy and I would appreciate your assistance in forwarding this to all CRP related staff within your agency.

- **Pharmacy Manager Position:** Please note that the CRP is short staffed at this time due to John Wall having taken a pharmacist position at Fort Lee. We are in the process of seeking part-time support and are recruiting to ensure that we are back to full capacity in Pharmacists as soon as possible. Your assistance in minimizing calls to the CRP and understanding of any minor delays during this period of transition is appreciated.

- **Financial Stability**: The CRP will end the fiscal year having operated within our approved allocation. We will have carry-over year-end balances that are attributed to the following:
  - Delays in being able to secure CMS endorsement of our State Pharmacy Assistance Plan (SPAP). This has been a labor intensive effort led the CO team of Michele Thomas, John Jackson and James Stone. See additional information on the SPAP included in this update.
  - Under-utilization of the CSB allocations, largely attributed to boards operating much of year without the benefit of the online rePortal system. See additional information about he rePortal system included in this update.

  We anticipate some reduction in the overall funding for the CRP in FY 08 due to the reduced revenue projections for the Commonwealth, but do not believe the reduction will have an impact

on the current fiscal stability of the CRP.

- **Online Report Resource - rePortal:** We now have a total of 33 boards enrolled in and utilization the online CRP tracking system - rePortal. James Stone was lead for this effort and the product provides each board access to current CRP utilization data - clinical and financial - as well as drug information sheets and various forms or charts that can assist staff and consumers. A rePortal PowerPoint Tutorial is now available to help new users gain familiarity with the system.

- **State Pharmacy Assistance Plan:** The SPAP process has advanced significantly in recent weeks. We have made a successful transition of data files to an intermediary, a critical step in establishing a pathway to CMS that will allow CRP medications provided to a Medicare Part D enrolled individuals that hits the donut hole to be credited toward the cost of True-Out-Of-Pocket (TROOP). Guidelines for this process will be forwarded to boards once all the pathway lines are finalized.

- **Wellness Products:** We have had a limited response to the $5,000 addition to each CSB draw for the purchase of wellness products, i.e. body mass indicator, glucometers, blood pressure meters, weight scales, smoking cessation products, and pill organizers. Please consider the benefit of these products in your overall medical support services for individuals that are accessing medications through the CRP. We welcome any suggestions regarding other wellness products that you may want to secure through this process.

- **Buprenorphine:** In an effort to promote access to modern, appropriate and effective Opioid addiction treatment, the CRP has developed policy for accessing Buprenorphine/Naxoloxone. Additionally, the Office of Substance Abuse is preparing a best practice guidance bulletin "Buprenorphine Products for the Pharmacologic Management of Opiate Addiction" that will be disseminated in the near future. Eligibility for accessing this medication is consistent with current CRP eligibility criteria. The Department will monitor individual board use of this new resource to determine the need for adjustments in the monthly draw for medications.

I appreciate the ongoing efforts at each board, within CO and at the CRP to gain maximum benefit from the services of this valuable resource. Looking forward to a new fiscal year with expectations of us achieving great successes. - thanks - frank

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"Envision the Possibilities" and Act